

Date of Approval NOV 9 2001

FREEDOM OF INFORMATION (FOI) SUMMARY

Ketamine Hydrochloride injection for cats and subhuman primates

ANADA 200-257

Vetrepharm Research, Inc.

119 Rowe Road

Athens, Georgia 30601

ANADA 200-257

FOIS-1

1. GENERAL INFORMATION

ANADA #: 200-257

Sponsor:

Vetrepharm Research, Inc.
119 Rowe Road
Athens, GA, U.S.A.
30601
DLC # 064847

Trade Name: Ketamine HCl

Generic Name: Ketamine hydrochloride injection USP

Dosage Form: Sterile Solution

How Supplied: 10 ml multiple doses vials

How Dispensed: Prescription

Amount of Active

Ingredients: Each ml contains ketamine hydrochloride equivalent to 100-mg ketamine base.

Route of

Administration: Intramuscular Injection

Species: Cats and subhuman primates

Labeled Dosage:

- **Cats:**

A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

- **Subhuman primates:**

The recommended restraint dosages for the following species are: *Cercocebus torquatus* (white-collared mangabey), *Papio cynocephalus* (yellow baboon), *Pan troglodytes verus* (chimpanzee), *Papio anubis* (olive baboon), *Pongo pygmaeus* (orangutan), *Macaca nemestrina* (pig-tailed macaque), 5 to 7.5 mg/kg; *Presbytis entellus* (entellus langur), 3 to 5 mg/kg; *Gorilla gorilla gorilla* (gorilla), 7 to 10

mg/kg; *Aotus trivirgatus* (night monkey), 10 to 12 mg/kg; *Macaca mulatta* (rhesus monkey), 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin), 13 to 15 mg/kg; *Macaca fascicularis* (crab-eating macaque), *Macaca radiata* (bonnet macaque), and *Saimiri sciureus* (squirrel monkey), 12 to 15 mg/kg.

A single intramuscular injection produces restraint suitable for TB testing, radiography, physical examination or blood collection.

Indications for Use:

Ketamine hydrochloride injection, USP may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

Pioneer Product:

Vetalar[®], (ketamine hydrochloride, 100 mg/mL), NADA 045-290 by Fort Dodge Animal Health.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, first GADPTRA Policy Letter), an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Vetrepharm Research, Inc. was granted a waiver February 6, 1998, from conducting an in vivo bioequivalence study with Ketamine Hydrochloride Injection. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient.

3. HUMAN SAFETY:

Human Safety Relative to Food Consumption:

Regarding consumption of drug residues in food, human safety data are not required since this drug is labeled for use in cats and subhuman primates not intended for food.

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:



This is an Abbreviated New Animal Drug Application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Ketamine Hydrochloride Injection (100 mg/ml), were established by demonstration of chemical equivalence to the pioneer product, Fort Dodge Animal Health's Vetalar® (ketamine hydrochloride, USP, 100 mg/ml, NADA 045-290).

This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered by intramuscular injection. The generic and pioneer products are both solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, in compliance with FDA policy promulgated to implement Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or in vivo bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Ketamine HCl is safe and effective for its labeled indications when used under its proposed conditions of use.

Mac File:
Ketavet 10mL Box (2).pm6
SEPT 11/01
revised from June 27, 2001

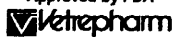
	Exp: Lot:		
	<p>For Intramuscular Use</p> <p>Store at room temperature 15-30°C (59 -86°F).</p> <p>Protect from light.</p> <p>DOSAGE: See package insert.</p> <p>For Use in Cats and Subhuman Primates Only. Not more than 0.1 mg/mL benzethonium chloride added as a preservative. Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not effect potency. Do not use if precipitate appears.</p>		<p>NDC 64847-034-10</p> <p>KETAMINE HCl  Ketamine HCl Inj., USP</p> <p>Equivalent to 100 mg/mL Ketamine 10 mL</p> <p>CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>ANADA 200-257 Approved by FDA</p> <p> Vetrepharm</p> <p>Distributed by: Vetrepharm Research, Inc. Athens, GA, U.S.A. 30601</p>

NDC 64847-034-10

KETAMINE HCl ®
Ketamine HCl Inj., USP
Equivalent to
100 mg/mL Ketamine
10 mL

CAUTION: Federal law restricts this
drug to use by or on the order of a
licensed veterinarian.

ANADA 200-257
Approved by FDA

 Vetrepharm

For Intramuscular Use
DOSAGE: See package insert.
For Use in Cats and Subhuman Primates Only.
Store at room temperature 15-30°C (59-86°F).
Protect from light.
Color of solution may vary from colorless to very
slightly yellowish and may darken upon prolonged
exposure to light. This darkening does not affect
potency. Do not use if precipitate appears.
Not more than 0.1 mg/mL benzethonium chloride
added as a preservative.

Distributed by:
Vetrepharm Research, Inc.
Athens, GA, U.S.A. 30601

LOT: _____
EXP: _____

Printed At 150%

Mac File Name: Ketavet 10mL Label (2).pm6

Label size: 2 15/16" x 1 1/16" (10mL)

Date: Sept 14, 2001

replaces June 27, 2001

Pantone colours Black, Green 341CV

ANADA 200-257, Approved by FDA

KETAMINE HCl KETAMINE HYDROCHLORIDE INJECTION, USP

Veterinary Injection for Intramuscular Use in Cats and Subhuman Primates Only

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

KETAMINE HCl is a rapid-acting, nonnarcotic, nonbarbiturate agent for anesthetic use in cats and for restraint in subhuman primates. It is chemically designated *d*/2-(*o*-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride and is supplied as a slightly acid (pH 3.5 - 5.5) solution for intramuscular injection in a concentration containing the equivalent of 100 mg ketamine base per milliliter and contains not more than 0.1 mg/mL benzethonium chloride as a preservative.

ACTION

KETAMINE HCl is a rapid-acting agent whose pharmacological action is characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, mild cardiac stimulation and respiratory depression. Skeletal muscle tone is variable and may be normal, enhanced or diminished. The anesthetic state produced does not fit into the conventional classification of stages of anesthesia, but instead KETAMINE HCl produces a state of unconsciousness which has been termed "dissociative" anesthesia in that it appears to selectively interrupt association pathways to the brain before producing somesthetic sensory blockade.

In contrast to other anesthetics, protective reflexes, such as coughing and swallowing are maintained under KETAMINE HCl anesthesia. The degree of muscle tone is dependent upon level of dose; therefore, variations in body temperature may occur. At low dosage levels there may be an increase in muscle tone and a concomitant slight increase in body temperature. However, at high dosage levels there is some diminution in muscle tone and a resultant decrease in body temperature, to the point where supplemental heat may be advisable.

In cats, there is usually some transient cardiovascular stimulation, increased cardiac output with slight increase in mean systolic pressure with little or no change in total peripheral resistance. At higher doses, the respiratory rate is usually decreased.

The assurance of a patent airway is greatly enhanced by virtue of maintained pharyngeal-laryngeal reflexes. Although some salivation is occasionally noted, the persistence of the swallowing reflex aids in minimizing the hazards associated with ptialism. Salivation may be effectively controlled with atropine sulfate in dosages of 0.04 mg/kg (0.02 mg/lb) in cats and 0.01 to 0.05 mg/kg (0.005 to 0.025 mg/lb) in subhuman primates.

Other reflexes, e.g., corneal, pedal, etc., are maintained during KETAMINE HCl anesthesia, and should not be used as criteria for judging depth of anesthesia. The eyes normally remain open with the pupils dilated. It is suggested that a bland ophthalmic ointment be applied to the cornea if anesthesia is to be prolonged.

Following administration of recommended doses, cats become ataxic in about 5 minutes with anesthesia usually lasting from 30 to 45 minutes at higher doses. At the lower doses, complete recovery usually occurs in 4 to 5 hours but with higher doses recovery time is more prolonged and may be as long as 24 hours.

In studies involving 14 species of subhuman primates represented by at least 10 anesthetic episodes for each species, the median time to restraint ranged from 1.5 [Aotus trivirgatus (night monkey) and Cebus capucinus (white-throated capuchin)] to 5.3 minutes [Macaca nemestrina (pig-tailed macaque)]. The median duration of restraint ranged between 20 and 55 minutes in all but five of the species studied. Total time from injection to end of restraint ranged from 43 [Saimiri sciureus (squirrel monkey)] to 183 minutes [Macaca nemestrina (pig-tailed macaque)] after injection. Recovery is generally smooth and uneventful. The duration is dose related.

By single intramuscular injection, KETAMINE HCl usually has a wide margin of safety in cats and subhuman primates. In cats, cases of prolonged recovery and death have been reported.

INDICATIONS

KETAMINE HCl may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

CONTRAINDICATIONS

KETAMINE HCl is contraindicated in cats and subhuman primates suffering from renal or hepatic insufficiency.

KETAMINE HCl is detoxified by the liver and excreted by the kidneys; therefore, any preexistent hepatic or renal pathology or impairment of function can be expected to result in prolonged anesthesia; related fatalities have been reported.

PRECAUTIONS

In cats, doses in excess of 50 mg/kg during any single procedure should not be used. The maximum recommended dose in subhuman primates is 40 mg/kg.

To reduce the incidence of emergence reactions, animals should not be stimulated by sound or handling during the recovery period. However, this does not preclude the monitoring of vital signs.

Apnea, respiratory arrest, cardiac arrest and death have occasionally been reported with ketamine used alone, and more frequently when used in conjunction with sedatives or other anesthetics. Close monitoring of patients is strongly advised during induction, maintenance and recovery from anesthesia.

ADVERSE REACTIONS

Respiratory depression may occur following administration of high doses of KETAMINE HCl. If at any time respiration becomes excessively depressed and the animal becomes cyanotic, resuscitative measures should be instituted promptly. Adequate pulmonary ventilation using either oxygen or room air is recommended as a resuscitative measure.

Adverse reactions reported have included emesis, salivation, vocalization, erratic recovery and prolonged recovery, spastic jerking movements, convulsions, muscular tremors, hypertonicity, opisthotonos, dyspnea and cardiac arrest. In the cat, myoclonic jerking and/or mild tonic convulsions can be controlled by ultrashort-acting barbiturates which should be given to effect. ~~The barbiturates should be administered intravenously at a dose level of one-sixth to one-fourth the usual dose for the product being used.~~ Acepromazine may also be used. However, recent information indicates that some phenothiazine derivatives may potentiate the toxic effects of organic phosphate compounds such as found in flea collars and certain anthelmintics. A study has indicated that ketamine hydrochloride alone does not potentiate the toxic effects of organic phosphate compounds.

ADMINISTRATION AND DOSAGE

KETAMINE HCl is well tolerated by cats and subhuman primates when administered by intramuscular injection.

Fasting prior to induction of anesthesia or restraint with KETAMINE HCl is not essential; however, when preparing for elective surgery, it is advisable to withhold food for at least six hours prior to administration of KETAMINE HCl.

Anesthesia may be of shorter duration in immature cats. Restraint in subhuman primate neonates (less than 24 hours of age) is difficult to achieve.

As with other anesthetic agents, the individual response to KETAMINE HCl is somewhat varied depending upon the dose, general condition and age of the subject so that dosage recommendations cannot be absolutely fixed.

Dosage -

Cats: A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

Subhuman Primates: The recommended restraint dosages of KETAMINE HCl for the following species are: *Cercocebus torquatus* (white-collared mangabey), *Papio cynocephalus* (yellow baboon), *Pan troglodytes verus* (chimpanzee), *Papio anubis* (olive baboon), *Pongo pygmaeus* (orangutan), *Macaca nemestrina* (pig-tailed macaque) 5 to 7.5 mg/kg; *Presbytis entellus* (entellus langur) 3 to 5 mg/kg; *Gorilla gorilla gorilla* (gorilla) 7 to 10 mg/kg; *Aotus trivirgatus* (night monkey) 10 to 12 mg/kg; *Macaca mulatta* (rhesus monkey) 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin) 13 to 15 mg/kg; and *Macaca fascicularis* (crab-eating macaque), *Macaca radiata* (bonnet macaque) and *Saimiri sciureus* (squirrel monkey) 12 to 15 mg/kg.

A single intramuscular injection produces restraint suitable for TB testing, radiography, physical examination or blood collection.

HOW SUPPLIED

KETAMINE HCl is supplied as the hydrochloride in concentrations equivalent to ketamine base.

Each 10 mL vial contains 100 mg/mL.

NDC 64847-034-10 - 10 mL - vial.

CLINICAL STUDIES

KETAMINE HCl has been clinically studied in subhuman primates in addition to those species listed under Administration and Dosage. Dosages for restraint in these additional species, based on limited clinical data, are: *Cercopithecus aethiops* (grivet), *Papio papio* (guinea baboon) 10 to 12 mg/kg; *Erythrocebus patas patas* (patas monkey) 3 to 5 mg/kg; *Hylobates lar* (white-handed gibbon) 5 to 10 mg/kg; *Lemur catta* (ringtailed lemur) 7.5 to 10 mg/kg; *Macaca fuscata* (Japanese macaque) 5 mg/kg; *Macaca speciosa* (stump-tailed macaque) and *Miopithecus talapoin* (mangrove monkey) 5 to 7.5 mg/kg; and *Symphalangus syndactylus* (siamangs) 5 to 7 mg/kg.

Distributed by:

 **Vetrepharm** Athens, GA, U.S.A., 30601

Taxonomy from "A Handbook of Living Primates" by Napier and Napier, Academic Press, New York, N.Y.

FORT DODGE®

FORT DODGE ANIMAL HEALTH
LABEL CONTROL

Revision: 1
 Operator: hal
 Date: 09/22/00
 Product I.D.#: 4408H
 Product Name: Ketaset
 Size: 1⁵/₁₆" x 1⁵/₁₆" x 2⁵/₈"
 Product Type: 100 mg/mL / Carton
 File Location: V1/PF/4408H/4408H
 To Disk: 11/02/00
 Rev. Level: H

■ PMS 287
 ■ PMS 185

30440810

Ketaset®
 KETAMINE HCl
 INJECTION, USP

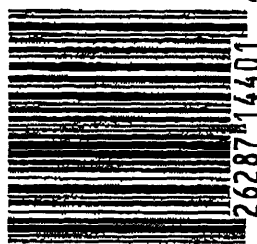
For Intramuscular Use
 Store at controlled room
 temperature 15° to 30°C
 (59° to 86°F). Protect
 from light.
DOSAGE: See package
 insert.
 For use in cats and
 subhuman primates only.

Ketaset®
 KETAMINE HCl
 INJECTION, USP

Ketaset®
 KETAMINE HCl
 INJECTION, USP

Ketaset®
 KETAMINE HCl
 INJECTION, USP

Not more than 0.1 mg/mL
 benzethonium chloride
 added as a preservative.
 Color of solution may vary
 from colorless to very
 slightly yellowish and may
 darken upon prolonged
 exposure to light. This
 darkening does not affect
 potency. Do not use if
 precipitate appears.
 See bottom flap for lot
 number and expiration date.



Equivalent to
 100 mg/mL
 Ketamine
 10 mL

CAUTION: Federal law
 restricts this drug to use by or
 on the order of a licensed vet-
 erinarian.

NADA 45-290
 Approved by FDA

Fort Dodge
 Animal Health
 Fort Dodge, Iowa 50501 USA

6523
 02860
 4408H

6523
 4408H



Post-it® Fax Note	7671	Date	9-13-01	# of pages	9
To	Dr. Fried	From	Ann H. Kinson		
Co./Dept.	CVM	Co.	FDAH		
Phone #	301-827-0165	Phone #	515-955-6061, 3806		
Fax #	301-827-1485	Fax #			



BASE LABEL BLEED AREA

For Intramuscular Use

DOSAGE: See package insert.

For Use in Cats and Subhuman Primates Only.

Store at controlled room temperature 15° to 30°C (59° to 86°F). Protect from light.

Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

4401G

NDC 0856-2013-01

Ketaset® CII
KETAMINE HCl INJ., USP

FORT DODGE®

Equivalent to
100 mg/mL

Ketamine
10 mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NADA 45-290, Approved by FDA

NADA 45-290, Approved by FDA



Ketaset® CII

KETAMINE HYDROCHLORIDE INJECTION, USP

**Veterinary Injection For Intra-
muscular Use in Cats and Sub-
human Primates Only**

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.

Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

DESCRIPTION

KETASET (ketamine hydrochloride injection, USP) is a rapid-acting, nonnarcotic, nonbarbiturate agent for anesthetic use in cats and for restraint in subhuman primates. It is chemically designated *d*/2-(*o*-chlorophenyl)-2-(methylamino)cyclohexanone hydrochloride and is supplied as a slightly acid (pH 3.5 to 5.5) solution for intramuscular injection in a concentration containing the equivalent of 100 mg ketamine base per milliliter and contains not more than 0.1 mg/mL benzethonium chloride as a preservative.

ACTION

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In contrast to other anesthetics, protective reflexes, such as coughing and swallowing are maintained under KETASET anesthesia. The degree of muscle tone is dependent upon level of dose; therefore, variations in body temperature may occur. At low dosage levels there may be an increase in muscle tone and a concomitant slight increase in body temperature. However, at high dosage levels there is some diminution in muscle tone and a resultant decrease in body temperature, to the point where supplemental heat may be advisable.

In cats, there is usually some transient cardiovascular stimulation, increased cardiac output with slight increase in mean systolic pressure with little or no change in total peripheral resistance. At higher doses the respiratory rate is usually decreased.

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By single intramuscular injection, KETASET usually has a wide margin of safety in cats and subhuman primates. In cats, cases of prolonged recovery and death have been reported.

INDICATIONS

KETASET may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

CONTRAINDICATIONS

KETASET is contraindicated in cats and subhuman primates suffering from renal or hepatic insufficiency.

KETASET is detoxified by the liver and excreted by the kidneys; therefore, any preexistent hepatic or renal pathology or impairment of function can be expected to result in prolonged anesthesia; related fatalities have been reported.

PRECAUTIONS

In cats, doses in excess of 50 mg/kg during any single procedure should not be used. The maximum recommended dose in subhuman primates is 40 mg/kg.

To reduce the incidence of emergence reactions, animals should not be stimulated by sound or handling during the recovery.

PRECAUTIONS (cont'd.)

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ADVERSE REACTIONS

Respiratory depression may occur following administration of high doses of KETASET (ketamine hydrochloride injection, USP). If at any time respiration becomes excessively depressed and the animal becomes cyanotic, resuscitative measures should be instituted promptly. Adequate pulmonary ventilation using either oxygen or room air is recommended as a resuscitative measure.

Adverse reactions reported have included emesis, salivation, vocalization, erratic recovery and prolonged recovery, spastic jerking movements, convulsions, muscular tremors, hypertonicity, opisthotonos, dyspnea and cardiac arrest. In the cat, myoclonic jerking and/or mild tonic convulsions can be controlled by ultrashort-acting barbiturates which should be given to effect. The barbiturates should be administered intravenously at a dose level of one-sixth to one-fourth the usual dose for the product being used. Acepromazine may also be used. However, recent information indicates that some phenothiazine derivatives may potentiate the toxic effects of organic phosphate compounds such as found in flea collars and certain anthelmintics. A study has indicated that ketamine hydrochloride alone does not potentiate the toxic effects of organic phosphate compounds.

ADMINISTRATION AND DOSAGE

KETASET is well tolerated by cats and subhuman primates when administered by intramuscular injection.

Fasting prior to induction of anesthesia or restraint with KETASET is not essential; however, when preparing for elective surgery, it is advisable to withhold food for at least six hours prior to administration of KETASET.

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Dosage —

Cats: A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

Subhuman Primates: The recommended restraint dosages of KETASET for the following species are: *Cercocebus torquatus* (white-collared mangabey), *Papio cynocephalus* (yellow baboon), *Pan troglodytes verus* (chimpanzee), *Papio anubis* (olive baboon), *Pongo pygmaeus* (orangutan), *Macaca nemestrina* (pig-tailed macaque) 5 to 7.5 mg/kg; *Presbytis entellus* (entellus langur) 3 to 5 mg/kg; *Gorilla gorilla gorilla* (gorilla) 7 to 10 mg/kg; *Aotus trivirgatus* (night monkey) 10 to 12 mg/kg; *Macaca mulatta* (rhesus monkey) 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin) 13 to 15 mg/kg; and *Macaca fascicularis* (crab-eating macaque), *Macaca radiata* (bonnet macaque) and *Saimiri sciureus* (squirrel monkey) 12 to 15 mg/kg.

A single intramuscular injection produces restraint suitable for TB testing; radiography, physical examination or blood collection.

HOW SUPPLIED

KETASET (ketamine hydrochloride injection, USP) is supplied as the hydrochloride in concentrations equivalent to ketamine base.

Each 10 mL vial contains 100 mg/mL.

NDC 0856-2013-01 — 10 mL — vial

CLINICAL STUDIES

KETASET has been clinically studied in subhuman primates in addition to those species listed under Administration and Dosage. Dosages for restraint in these additional species, based on limited clinical data, are: *Cercopithecus aethiops* (grivet), *Papio papio* (guinea baboon) 10 to 12 mg/kg; *Erythrocebus patas patas* (patas monkey) 3 to 5 mg/kg; *Hylobates lar* (white-handed gibbon) 5 to 10 mg/kg; *Lemur catta* (ringtailed lemur) 7.5 to 10 mg/kg; *Macaca fuscata* (Japanese macaque) 5 mg/kg; *Macaca speciosa* (stump-tailed macaque) and *Miopithecus*

(white-handed gibbon) 5 to 10 mg/kg;
Lemur catta (ringtailed lemur) 7.5 to 10
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 macaque) 5 mg/kg; *Macaca speciosa*
 (stumptailed macaque) and *Miopithecus*
talapoin (mangrove monkey) 5 to 7.5
 mg/kg; and *Symphalangus syndactylus*
 (siamangs) 5 to 7 mg/kg.

Taxonomy from "A Handbook of Living
 Primates" by Napier and Napier, Academic
 Press, New York, N.Y.

FORT DODGE **®** **FORT DODGE ANIMAL HEALTH**
LABEL CONTROL

Revision: 2
 Operator: hal
 Date: 8/3/99

PMS 107
PMS 185

000000

For Intramuscular Use
DOSAGE: See package insert.
For Use in Cats and
Subhuman Primates Only.

NDC 0856-2013-01
Ketaset[®] III
KETAMINE HCl INJ., USP
FORT DODGE[®]

Lot
 Exp. Date
44016

F D ANIMAL HEALTH (U.S.A.) 5 10 5 mg/kg; *Myiurus* 0.8321 (white-handed gibbon) 5 to 10 mg/kg; *Lemur catta* (ringtailed lemur) 7.5 to 10 mg/kg; *Macaca fuscata* (Japanese macaque) 5 mg/kg; *Macaca speciosa* (stump-tailed macaque) and *Miopithecus talapoin* (mangrove monkey) 5 to 7.5 mg/kg; and *Symphalangus syndactylus* (siamangs) 5 to 7 mg/kg.

Taxonomy from "A Handbook of Living Primates" by Napier and Napier, Academic Press, New York, N.Y.

FORT DODGE®

FORT DODGE ANIMAL HEALTH LABEL CONTROL

Revision: 2
Operator: hal
Date: 9/2/00

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For Intramuscular Use

NDC 0856-2013-01

DOSAGE: See package insert.

Ketaset® III

For Use in Cats and
Subhuman Primates Only.

KETAMINE HCl INJ., USP

FORT DODGE®

Store at controlled room temperature 15° to 30°C (59° to 86°F). Protect from light.

Equivalent to
100 mg/mL
Ketamine
10 mL

Not more than 0.1 mg/mL
benzethonium chloride added
as a preservative.

CAUTION: Federal law restricts this
drug to use by or on the order of a
licensed veterinarian.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

NADA 45-290, Approved by FDA

Lot

Exp. Date

44016